510(k) Summary

AUG 14 2012

Thommen Medical AG

K121334

VARIOeco

June 27, 2012

ADMINISTRATIVE INFORMATION

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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name: VARIOeco
Common Name: Dental implant abutment

Classification Name: Endosseous dental implant abutment
Classification Regulation: 21 CFR 872.3630, Class II
Product Code: NHA

Classification Panel: Dental Products Panel
Reviewing Branch: Dental Devices Branch

INTENDED USE

Thommen VARIOeco dental implant abutments are intended to be used in conjunction with Thommen System dental implants in the maxillary and/or mandibular arch to provide support for crowns, bridges and overdentures.

DEVICE DESCRIPTION

VARIOeco abutments are titanium dental implant abutments for use with Thommen System dental implants for fabrication of porcelain-fused-to-metal (PFM) restorations. VARIOeco includes two abutment designs, one for single tooth (crown) and one for multi-tooth (bridge) restorations. A laboratory burn-out cap and abutment screw are provided together with the abutment in the VARIOeco set. Both VARIOeco abutment designs are provided in five platform diameters (3.5, 4.0, 4.5, 5.0 and 6.0 mm) corresponding to Thommen System dental implants (ELEMENT, CONTACT and ONETIME).

EQUIVALENCE TO MARKETED DEVICE

Thommen Medical AG has submitted information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, VARIOeco is substantially equivalent in indications and design principles to the following legally marketed predicate devices:

Thommen Medical AG, SPI® EASY 4.0 Abutment - K071453,
Thommen Medical AG, SPI® Dental Implant Abutments - K031747,
Altatec GmbH, CAMLOG® Vario SR Abutments - K103252,

The subject VARIOeco abutment and predicates straight SPI EASY Abutment and straight VarioSR Abutment are all titanium abutments with a burn-out plastic sleeve for restoration fabrication.

The subject device and the predicate devices have the same intended use and have the same technological characteristics. They encompass the same range of physical dimensions, including platform diameter, abutment height and abutment/implant interface. The subject and predicate devices are packaged in similar materials and sterilized using similar methods. Any differences in the technological characteristics do not raise new issues of safety or efficacy.

	Subject Device	Predicate Devices		
	Thommen Medical AG VARIOeco	Thommen Medical AG SPI® EASY 4.0 Abutment K071453	Thommen Medical AG SPI® Dental Implant Abutments K031747	Altatec GmbH CAMLOG® Vario SR Abutments K103252
Indications for Use	Thommen VARIOeco dental implant abutments are intended to be used in conjunction with Thommen System dental implants in the maxillary and/or mandibular arch to provide support for crowns, bridges and overdentures.	The Thommen SPI® EASY Ø 4.0 Abutment is intended to be used in conjunction with SPI® System dental implants in the maxillary and/or mandibular arch to provide support for crowns, bridges or. overdentures.	Thommen SPI® Dental Implant Abutments are intended to be used in conjunction with SPI® System dental implants in the maxillary and/or mandibular arch to provide support for crowns, bridges or overdentures.	CAMLOG® Vario SR components for crown and bridge restorations: - Occlusal screw-retained crown, bridge and bar constructions on CAMLOG® implants (with J and K article numbers) in the anterior and posterior region of the maxilla and mandible CAMLOG® Vario SR components for bar restorations: - Anchorage of implant-supported full dentures for the edentulous maxilla and mandible in combination with 2, 4 or more CAMLOG® implants (with J and K article numbers)
Restoration	Single or multi-unit	Single or multi-unit	Single or multi-unit	Single or multi-unit
Abutment (Ø mm)	3.5, 4.0, 4.5, 5.0, 6.0	4.0	3.5, 4.5, 5.0, 6.0	3.8, 4.3, 5.0, 6.0
Material	CPTi Gr 4 – abutment POM – Burn-out sleeve	CPTi Gr 4 – abutment POM – Burn-out sleeve	CPTi Gr 4 – abutment POM – Burn-out sleeve	CPTi Gr 4 - abutment Ti-6Al-4V - abutment POM – Burn-out sleeve

Overall, VARIOeco has the following similarities to the predicate devices:

- has the same intended use,
- uses the same operating principle,
- incorporates the same basic design,
- incorporates the same or very similar materials, and
- has similar packaging and is sterilized using the same materials and processes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 14 2012

THOMMEN Medical, AG
C/O Ms. Linda K. Schulz
PaxMed International, Limited Liability Company
11234 El Camino Real, Suite 200
San Diego, California 92130

Re: K121334
Trade/Device Name: VARIOeco
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: June 27, 2012
Received: June 28, 2012

Dear Ms. Schulz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K121334

Device Name: VARIOeco

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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